

REMARKS

Applicants again wish to thank the Examiner for taking time out of his busy schedule to interview this case with Dr. Bob Hrubiec, Esq. and Dr. John Mallamo, and Applicants' undersigned representative on July 10, 2006. Dr. Hrubiec, in particular, wishes to express his great appreciation of the Examiner's expedient handling of this application, and the courtesy and cooperation extended at the interview.

Status of Claims

Claims 78 to 87 are currently pending. No claims are added or cancelled. As suggested by the Examiner, claims 84 and 87 have been amended to clarify that "Form I (-)-modafinil" refers to "a Form I *polymorph* of (-)-modafinil." Similar amendments were also made to claims 85 and 86, to assure that these claims are properly dependent from claim 84. No change in claim scope is intended by these amendments.

Summary of the Invention

Pending claims 78 to 87 are directed to a stable and particularly advantageous polymorphic form of the levorotatory enantiomer of modafinil, denominated in the instant application as the "Form I" polymorph. Independent claim 78 describes the polymorph as one that produces a powder X-ray diffraction (PXRD) spectrum comprising intensity peaks at the interplanar spacings: 8.54, 4.27, 4.02, 3.98 (Å). Independent claim 80 describes the polymorph as one that produces a powder X-ray diffraction spectrum with reflections at 15.4, 31.1, 33.1 and 33.4 degrees 2θ . Claim 87 is directed to a method for preparing the Form I polymorph.

Rejection Under 35 U.S.C. § 102

In the Office Action dated July 7, 2006, claims 78 to 86 stand rejected as anticipated by Lafon, U.S. Patent No. 4,927,855 ("the Lafon '855 patent"). The Office Action asserts that the mere fact that the reference doesn't mention this polymorph does not distinguish it from the instant claims as it is "inherently there."

As discussed during the interview, the declarative evidence already of record establishes that various polymorphic forms of (-)-modafinil may be produced when the compound is "recrystallized from ethanol," as taught in the Lafon '855 patent. Since practice of the teachings

of the '855 patent does not *necessarily* result in the claimed Form I polymorph, Applicants respectfully traverse this rejection.

As stated in M.P.E.P. § 2112, the fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)¹ (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *see also, Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 1000 (Fed. Cir. 2006) (“anticipation by inherent disclosure is appropriate only when the reference discloses prior art that *must necessarily* include the unstated limitations.” (*emphasis added*)). To establish inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Inherent anticipation may not be established by probabilities or possibilities; the mere fact that a certain thing (*i.e.*, a particular polymorph) *may* result from a given set of circumstances is not sufficient to meet the threshold showing needed to establish anticipation by inherency. *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1376 (Fed. Cir. 2001).

The Lafon '855 patent does not expressly teach or describe the claimed Form I polymorph of (-)-modafinil. Applicants have established by way of declarative evidence that recrystallization of (-)-modafinil from ethanol, as taught by the Lafon '855 patent, leads to production of various polymorphic forms of the compound, depending upon the particular conditions employed to perform the recrystallization. The Lafon '855 patent is silent regarding the conditions that were utilized to perform the recrystallization. Thus, it cannot be said that practicing the teachings of the Lafon '855 patent would necessarily result in a polymorphic form of (-)-modafinil as recited in the pending claims.

Thus, the facts of the instant situation are quite similar to those underlying the *Glaxo, Inc. v. Novopharm Ltd.* case discussed during the interview.² In that case, the claims at issue were directed to a particular crystalline form of ranitidine hydrochloride, designated as Form 2.

1 Copies of all cases cited herein are enclosed herewith, for the Examiner's convenience.

2 830 F. Supp 871 (E.D.N.C. 1993), *aff'd* 52 F.3d 1043, 1048 (Fed. Cir. 1995).

Novopharm argued that the claims were invalid as inherently anticipated by a prior art method of producing ranitidine hydrochloride, because it had repeatedly followed the prior art method, and always obtained Form 2. The patentee established, however, that minor variations in the prior art process resulted in production of a different crystalline form, designated as Form 1. The court found these minor variation to be within the teaching of the prior art, and concluded that since the evidence did not support a finding that the claimed Form 2 *invariably* results from the practice of the prior art method, Novopharm had failed to carry its burden of proving inherency. *Id.*, 830 F. Supp. at 877.

Applicants respectfully submit that the same conclusion is appropriate here. The '855 patent fails to *expressly* teach or suggest the Form I polymorph of (-)-modafinil that is the subject of the pending claims, because all of the claim elements are not disclosed. The declarative evidence establishes that the claimed Form I polymorph of (-)-modafinil is NOT the inevitable or necessary result flowing from the teaching or practice of the Lafon '855 patent, because different polymorphs are produced, depending upon the particular conditions employed to perform the recrystallization. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102 over the Lafon '855 patent.

Rejections Under 35 U.S.C. § 103

In the Office Action dated July 7, 2006, claims 78 to 87 stand rejected as obvious over the Lafon '855 patent, optionally in view of Broquaire et al, U.S. Patent No. 6,992,219 ("Broquaire"). Applicants respectfully traverse these rejections.

Statement Concerning Common Ownership of the Claimed Invention and Broquaire

As a preliminary matter, Applicants respectfully assert that Broquaire is excluded from being considered prior art by 35 U.S.C. § 103(c). In this connection, Section 103(c) provides that "[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Broquaire qualifies as prior art to the instant invention only under 35 U.S.C. § 102(e). The instant application is assigned to Cephalon France and Organisation de Synthèse Mondaile

Orsymonde, as recorded in the PTO at Reel No. 017132, Frame No. 0061. Moreover, the invention claimed in the present application was subject to an obligation of assignment to Cephalon France and/or Organisation de Synthese Mondaile Orsymonde at the time the invention was made. Similarly, as stated on its face, Broquaire is also assigned to Cephalon France and Organisation de Synthese Mondaile Orsymonde. Since the instant application and Broquaire were co-owned or subject to an obligation of assignment to the same person at the time the invention was made, Applicants respectfully submit that Broquaire is not available as prior art to the instant application under 35 U.S.C. § 103(c).

The Office Action dated July 7, 2006 further implies, however, that claims 78 to 86 are rendered obvious by the Lafon '855 patent alone. In this regard, the Office Action asserts that it would have been *prima facie* obvious to use the process described in the Lafon '855 patent "to obtain various polymorphs, including the one claimed herein." Applicants respectfully traverse this rejection.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. M.P.E.P. § 2143.03 (*citing In re Royka*, 490 F. 2d 921 (CCPA 1974)). As discussed above, there is no teaching or suggestion of the claimed Form I polymorph of (-)-modafinil, either expressly or inherently, in the Lafon '855 patent. Although the reference states that a crystalline form of (-)-modafinil is obtained from Preparation I, it does not indicate whether the product is a polymorph, or some other crystalline form. The patent is completely devoid of any X-ray diffraction data that could be used to identify a particular polymorphic form of (-)-modafinil. Indeed, the reference does not even suggest that (-)-modafinil may exist in different polymorphic forms, much less describe the particular Form I polymorph of (-)-modafinil that is the subject of the pending claims. Accordingly, Applicants respectfully submit that the Lafon '855 patent fails to teach or suggest all the limitations set forth in the pending claims, and cannot render the claimed subject matter *prima facie* obvious.

As discussed during the Examiner's interview, the situation at hand is similar to that presented in the case of *In re Cofer*, 354 F.2d 664 (CCPA 1966). In that case, both the examiner and the Board asserted that "merely changing the form, purity or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable." *Id.*, 354 F.2d at 667. The CCPA reversed, however, because the Board

“failed to address itself to other factors which must be given weight in determining whether the subject matter as a whole would have been obvious, namely, whether the prior art suggests the particular structure or form of the compound or composition as well as suitable methods of obtaining that structure or form.” *Id.*, 354 F.2d at 668. The court went on to state that “the record fails to support a holding that those skilled in the art should have known that [the compound] would exist in crystalline form or that it would be known how to obtain such crystals.” *Id.*

The same may be said of the rejection proffered in the Office Action. The Lafon ‘855 patent fails to even teach that (-)-modafinil may exist in polymorphic form, much less the particular form recited in Applicants’ claims, or provide any guidance to those of skill in the art how such a polymorph may be obtained.

Moreover, the court’s holding in *In re Cofer* does not stand in isolation, but has been followed in later cases, also discussed during the interview on July 10, 2006, to similar results. In the case of *In re Irani*,³ for example, the patent claims at issue were directed to a purer form of a prior art product. The CCPA found that the claimed form did not exhibit any unexpectedly different characteristics nor any patentably significant change in properties or utility, as compared with the prior art product. *Id.*, 427 F.2d at 808. Nonetheless, the court, following *In re Cofer*, held the claimed crystalline form to be nonobvious because “we are not convinced that the references of record would lead one of ordinary skill in the art to expect that [the compound] would exist in a crystalline, anhydrous form or, assuming such an expectation, that the references would render obvious a method by which such [compound] could be produced.” *Id.*

Similarly, the Court of Appeals for the Federal Circuit, in an unpublished opinion, relied on *In re Cofer* to find claims to a crystalline monohydrate form of cefadroxil monohydrate nonobvious. *Bristol-Myers Co. v. ITC*, 15 U.S.P.Q.2d 1258 (Fed. Cir. 1989). As stated by the court, “[i]t is insufficient that the prior art shows methods that some (but not all) chemists were able to modify, to produce the [claimed] crystalline form. There must be a suggestion or teaching in the prior art that the [claimed] crystal structure could or should be made, whether by manipulation or the [cited prior art] processes, or by any other process.” Since the record failed to show that there was “an affirmative suggestion or teaching in the prior art whereby it would

3 427 F.2d 806 (CCPA 1970).

DOCKET NO.: CP247 (CEPF-0006)
Application No.: 10/539,918
Office Action Dated: July 7, 2006

PATENT

have been obvious to make the new monohydrate," and not simply the absence of any obstacle to doing so, the court found the claimed monohydrate to be patentable.

The Lafon '855 patent fails to teach or suggest that (-)-modafinil may exist in the crystalline form set forth in the pending claims, that the claimed form could or should be made, or any methods for doing so. Thus, the facts are similar to those in *In re Cofer*, *In re Irani*, and *Bristol-Myers v. ITC*, as discussed above. In each of those cases, the court found the claimed subject matter to be nonobvious because of a similar lack of teaching or suggestion of the invention defined by the claims. Applicants respectfully submit that the same conclusion is proper on the instant facts. Accordingly, withdrawal of the rejection under 35 U.S.C. § 103 over the Lafon '855 patent is respectfully requested.

Conclusion

In light of the foregoing, Applicants respectfully submit that the pending claims are in condition for allowance. Accordingly, a Notice of Allowance for pending claims 78 to 87 is respectfully requested.

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